

REMARKS

The final Office Action of January 11, 2007, has been received and reviewed.

Claims 1-38 are currently pending and under consideration in the above-referenced application. Each of claims 1-38 stands rejected.

Reconsideration of the above-referenced application is respectfully requested.

Previous Amendment

Please note that a revised amendment was submitted in the above-referenced application on October 20, 2006, in response to a Notice of Non-Compliant Amendment. The Amendment of October 20, 2006, has not been acknowledged. If the Amendment of October 20, 2006, has, for some reason, not been entered into the Office file for the above-referenced application, the undersigned attorney would be happy to provide another copy of that Amendment to the Office.

Supplemental Information Disclosure Statement

Also, a Supplemental Information Disclosure Statement was filed in the above-referenced application on September 23, 2002, but the undersigned attorney has not yet received any indication that the references cited in that Supplemental Information Disclosure Statement have been considered in the above-referenced application. For the sake of convenience, another copy of the September 23, 2002, Supplemental Information Disclosure Statement, its accompanying Form PTO/SB/08A, and a USPTO date-stamped postcard evidencing receipt of the Supplemental Information Disclosure Statement and Form PTO/SB/08A by this Office are enclosed. It is respectfully requested that an initialed copy of the PTO/SB/08A evidencing consideration of the cited references be returned to the undersigned attorney.

Rejections under 35 U.S.C. § 112, Second Paragraph

Claims 24-30, 36, and 37 have been rejected under 35 U.S.C. § 112, second paragraph, for reciting subject matter that is purportedly indefinite. Specifically, it has been asserted that the structure that has been recited with respect to the respiratory flow component of these claims, which is an element that is not positively set forth in the claims, is ambiguous.

The standard that applies to these rejections is: would one of ordinary skill in the art, in view of the description that has been provided, understand the scope of the subject matter recited in claims 24-30, 36, and 37? M.P.E.P. § 2173.02.

The body of independent claim 1, as proposed to be amended herein, provides one of ordinary skill in the art with an understanding of the manner in which the recited transducer is to be assembled with a respiratory flow component. Specifically, independent claim 1 recites that a radiation source is “oriented to emit” radiation through a window of the respiratory flow component to a luminescable composition. Additionally, the detector of amended independent claim 1 is “oriented toward the window” to sense radiation emitted by the luminescable composition, through the window of the respiratory flow component.

Furthermore, one of ordinary skill in the art would readily understand from the language of claims 24-30 that all remaining reference in claims 24-30 to the features of a respiratory flow component merely provide context and to define the elements that have been positively set forth in claims 24-30. In this regard, the elements to which objections have been raised clearly convey the scope and meaning of each of claims 24-30 to one of ordinary skill in the art.

Independent claim 36 has been amended similarly to independent claim 1. Reference to features of the respiratory flow component, including the luminescable composition thereof, is useful for providing one of ordinary skill in the art with an understanding of one or more elements of the transducer.

As the objected-to language of each of claims 24-30, 36, and 37 provides one of ordinary skill in the art with a clear understanding of the scope of each of these claims, it is respectfully submitted that each of these claims complies with the definiteness requirement of 35 U.S.C. § 112, second paragraph, it is respectfully submitted that the 35 U.S.C. § 112, second paragraph rejections of claims 24-20, 36, and 37 should be withdrawn, and each of these claims should be allowed.

Rejections under 35 U.S.C. § 103(a)

Claims 1-38 stand rejected under 35 U.S.C. § 103(a).

The standard for establishing and maintaining a rejection under 35 U.S.C. § 103(a) is set forth in M.P.E.P. § 706.02(j), which provides:

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

Stanley in View of Knodle

Claims 1-10, 13-15, and 17-37 stand rejected under 35 U.S.C. § 103(a) for reciting subject matter which is assertedly unpatentable over the subject matter taught in U.S. Patent 3,725,658 to Stanley et al. (hereinafter "Stanley"), in view of teachings from U.S. Patent 4,914,720 to Knodle et al. (hereinafter "Knodle").

Stanley teaches an integral side stream monitoring apparatus that employs luminescence quenching technology for detecting changes in oxygen present in diverted respiratory samples. As evidenced by FIG. 1 of Stanley, a source 20 and detector 21 are positioned on opposite sides of a glass tube 14 to facilitate the excitation and sensing of radiation from a sensor film 15. *See also*, col. 5, lines 28-58. The source 20 is positioned within a first cavity 12 and oriented toward a first side, or window, of the glass tube 14, while the detector 21 is positioned within a second cavity 13 and oriented toward a second side, or window, of the glass tube 14.

In another embodiment, shown in FIG. 2 of Stanley, the source 20 and detector 21 are positioned on opposite sides of a plate 29 that conveys radiation from a tube 24. Thus, in the embodiment shown in FIG. 2, neither the source 20 nor the detector 21 is oriented toward a window.

Knodle teaches an infrared carbon dioxide cuvette that is configured for placement directly along a breathing tube. Accordingly, the cuvette of Knodle is part of a so-called “mainstream” sensor. A complementarily configured transducer of that sensor is configured for assembly with and disassembly from the cuvette.

It is respectfully submitted that there are several reasons that a *prima facie* case of obviousness has not been established against any of claims 1-10, 13-15, or 17-37.

First, it is respectfully submitted that both Stanley and Knodle do not teach or suggest each and every element of several claims of the above-referenced application.

Again the teachings of Stanley are limited to oxygen sensors that lack transducers that are separate from and configured for assembly with respiratory flow components. Rather, the source and detector of Stanley, which are positioned on opposite sides of a tube or plate to detect luminescence quenching, are integral parts of the disclosed device. The transducers taught in Knodle are configured to monitor carbon dioxide by directing infrared radiation completely through a cuvette so that the amount of attenuation of the radiation can be determined to provide an indication of the amount of carbon dioxide in a respiratory sample. As such, like the source and detector of Stanley, the teachings of Knodle are limited to a transducer that positions n which the source and detector on opposite sides of a cuvette.

In view of the foregoing, it is apparent that Stanley and Knodle lack any teaching or suggestion of a transducer with a source and detector that are oriented toward an exterior surface of the same window. More specifically, neither Stanley nor Knodle teaches or suggests a transducer with a source that is oriented toward an exterior surface of a window of a respiratory flow component to direct radiation directly through a thickness of the window to a luminescable composition adjacent to an opposite, interior surface of the window, as well as a detector that is oriented toward the exterior surface of the same window to sense radiation emitted by the luminescable composition, through the window.

Moreover, neither Stanley nor Knodle teaches or suggests a transducer with a detector that is configured to communicate with a processor configured to increase a signal-to-noise ratio of a signal indicative or an intensity of at least one wavelength of electromagnetic radiation

emitted by a luminescable composition, as required by claim 3. The teachings of Stanley regarding signal-to-noise ratios are limited to the recognition that a high ratio is desirable.

Stanley and Knodle also lack any teaching or suggestion of a transducer that includes a detector that is configured to communicate with a processor that operates under different processing protocols depending upon the monitored oxygen concentration, as recited in claim 5.

Claims 6 and 7 are directed to allowable subject matter since Stanley and Knodle both lack any teaching or suggestion of a transducer with a detector that comprises a photodiode or a transducer that comprises a PIN silicon photodiode, respectively.

With respect to the subject matter recited in claim 17, neither Stanley nor Knodle teaches or suggests a transducer with a second radiation source that emits at least a calibration wavelength of electromagnetic radiation. The teachings of Stanley are instead limited to calibration of a sensor with gas mixtures including known concentrations of oxygen.

Claim 18, which depends from claim 17, is also allowable since neither Stanley nor Knodle includes any teaching or suggestion of a transducer with a second radiation source that emits calibration radiation that will not cause a luminescable material of a sensor that is configured for assembly with the transducer to luminesce.

With respect to the subject matter recited in claims 25-30, even assuming, *arguendo*, that Stanley suggests the desirability of including a temperature control component in a transducer, neither Stanley nor Knodle teaches or suggests a transducer with a heater component that is configured to contact a thermal capacitor upon assembly of the transducer with a respiratory flow component, as recited in claim 25; a transducer with a temperature control component exposed therethrough, as recited in claim 26; a transducer with a heater component that is configured to be biased against a thermal capacitor of a respiratory flow component, as recited in claim 27; a transducer with a heater component that includes a thick film heater, as recited in claim 28; or a transducer with a temperature sensor that senses a temperature of a heater component, a capacitor, or a luminescable composition, as recited in claim 30.

Independent claim 36 is allowable since neither Stanley nor Knodle teaches or suggests a transducer with a detector that is substantially stable for about eight hours or more. Additionally, Stanley and Knodle both lack any teaching or suggestion of a transducer with a detector that is

oriented toward an exterior surface of a window of a respiratory flow component to direct radiation directly through a thickness of the window to a luminescable composition adjacent to an opposite, interior surface of the window.

Claim 37, which is allowable for depending from claim 36, is also allowable because Stanley and Knodle both lack any teaching or suggestion of a transducer with a detector that “has a stability of about ± 2 torr over eight hours at an atmospheric oxygen concentration.”

It is, therefore, respectfully submitted that a *prima facie* case of obviousness has not been established against any of claims 1-10, 13-15, and 17-35. Therefore, under 35 U.S.C. § 103(a), the subject matter recited in each of claims 1-10, 13-15, and 17-35 is allowable over the subject matter taught in Stanley and Knodle.

Second, one of ordinary skill in the art wouldn’t have had the benefit of hindsight that the claims of the above-referenced application have provided to the Office. Without such knowledge, one of ordinary skill in the art wouldn’t have been motivated to combine the oxygen sensor of Stanley with the carbon dioxide sensor of Knodle in the manner that has been asserted.

In particular, the claims of the above-referenced application are directed to transducers. As the side stream monitoring apparatus of Stanley does not include a transducer, the Office has relied upon Knodle for its disclosure of a multi-component respiratory sensor that includes a transducer that is configured for assembly with a “mainstream” cuvette. It is respectfully submitted that one of ordinary skill in the art wouldn’t have been motivated to add complexity to the integral side stream, luminescence quenching type oxygen monitoring apparatus of Stanley by incorporating various components thereof into a separate transducer and cuvette, particularly from an attenuated radiation type carbon dioxide sensor of the type taught in Knodle.

It is further submitted that one of ordinary skill in the art would have understood the inventive effort required to adapt a luminescence quenching type sensor from the context of side stream monitoring, in which very small respiratory samples are used, to a mainstream device, in which monitoring is conducted on a much large sample – all respiratory gases.

Furthermore, one of ordinary skill in the art wouldn’t have been motivated to combine teachings from a luminescence quenching apparatus of the type taught in Stanley with teachings

that pertain to an infrared sensing device, such as that taught in Knodle. This is because the sample container of the luminescence quenching apparatus of Stanley is coated with a luminescable material, which one of ordinary skill in the art would expect to disrupt transmission of radiation from a first location outside the tube, through the tube and a respiratory sample therein, to an opposite, second location outside the tube. The infrared sensing device of Knodle requires such an unobstructed optical path through the sample container.

Third, one of ordinary skill in the art wouldn't have had any reason to expect that the purported combination of teachings from Stanley and Knodle would have been successful, particularly when the teachings of these references are considered in their entireties, as required by M.P.E.P. § 2141.02. For example, the luminescent material-coated tube, sensor, and detector of Stanley are part of an integral unit; thus, there would be no reason to couple the transducer of Knodle to the apparatus of Stanley. Even assuming, for the sake of argument, that the transducer of Knodle could be coupled to the apparatus of Stanley, the wavelengths that are generated and detected by the source and detector of Knodle's transducer would not excite the luminescent material within the apparatus of Stanley or detect fluorescence from the luminescent material.

Further, the presence of luminescable material on the surfaces of the tube would interfere with the transmission of infrared radiation completely through the tube, as would be required for the transducer taught in Knodle to work with the sample tube of Stanley. Therefore, one of ordinary skill in the art would not have any reason to expect that features from the mainstream infrared sensor taught in Knodle could be incorporated into the side stream luminescence quenching sensor taught in Stanley.

Stanley, Knodle, and Yafuso

Claims 11 and 12 are rejected under 35 U.S.C. § 103(a) for being drawn to subject matter that is allegedly unpatentable over the teachings of Stanley, in view of teachings from Knodle and, further, in view of the subject matter taught in U.S. Patent 4,849,172 to Yafuso et al. (hereinafter "Yafuso").

Yafuso does not remedy the aforementioned deficiencies of Stanley and Knodle. Therefore, claims 11 and 12 are both allowable, among other reasons, for respectively depending directly and indirectly from claim 1, which is allowable.

Stanley, Knodle, and Hauenstein

Claim 16 has been rejected under 35 U.S.C. § 103(a) for being drawn to subject matter which is assertedly unpatentable over that taught in Stanley, in view of teachings from Knodle and, further, in view of the teachings of U.S. Patent 4,861,727 to Hauenstein et al. (hereinafter "Hauenstein").

Hauenstein does not remedy the aforementioned deficiencies of Stanley and Knodle. Therefore, claim 16 is allowable, among other reasons, for depending directly from claim 1, which is allowable.

Stanley, Knodle, and Alcala

Claim 38 stands rejected under 35 U.S.C. § 103(a) for being reciting subject matter that is allegedly unpatentable over the teachings of Stanley, in view of teachings from Knodle and, further, in view of the teachings of U.S. Patent 5,315,993 to Alcala et al. (hereinafter "Alcala").

Claim 38 is allowable, among other reasons, because Alcala does not remedy the aforementioned deficiencies of Stanley and Knodle in supporting a *prima facie* case of obviousness.

Additionally, it is respectfully submitted that Stanley and Knodle both lack any teaching or suggestion of a transducer with a source and detector that are oriented toward an exterior surface of the same window of a respiratory flow component, as recited in independent claim 38, as proposed to be amended herein.

It is respectfully requested that the 35 U.S.C. § 103(a) rejections of claims 1-38 be withdrawn, and that each of these claims be allowed.

Entry of Amendments

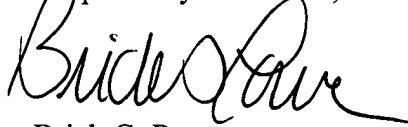
Entry of the proposed claim amendments is respectfully requested. It is respectfully submitted that, by entering the proposed amendments to the claims, all of the claims would be placed in condition for allowance, eliminating any issues that remain for appeal. It is further submitted that the revisions to the claims do not introduce new matter into the above-referenced application.

In the event that the proposed claim amendments are not entered, it is respectfully requested that they be entered upon the filing of a Notice of Appeal in the above-referenced application.

CONCLUSION

It is respectfully submitted that each of claims 1-38 is allowable. An early notice of the allowability of each of these claims is respectfully solicited, as is an indication that the above-referenced application has been passed for issuance. If any issues preventing allowance of the above-referenced application remain which might be resolved by way of a telephone conference, the Office is kindly invited to contact the undersigned attorney.

Respectfully submitted,



Brick G. Power
Registration No. 38,581
Attorney for Applicants
TRASKBRITT, PC
P.O. Box 2550
Salt Lake City, Utah 84110-2550
Telephone: 801-532-1922

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